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EXAMINER	
GLASS, RUSSELL S	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,872	SEELINGER, PAUL	
	Examiner	Art Unit	
	Russell S. Glass	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/18/05 6/2/05 etc*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 6, 7, 14-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, applicant's use of the phrase "related to" in claim 6(c) renders the scope of the claim indefinite. It is unclear what information could be related to re-packaging, labeling, and solution admixture activities.

Claim 15 is also indefinite because of the phrase "previously known". It is unclear who must previously know the product recall data to practice the method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-4, 9-13 rejected under 35 U.S.C. 102(b) as being anticipated by Mayaud, (U.S. 5,845,255).**

3. As per claim 1, Mayaud discloses an institutional level data repository system for medication product information, said system comprising:

a) a database containing medical product information, (Mayaud, Col. 48, lines 9-col. 49, line 67) (drug information is considered to be product information).

Medical product information comprising one or more of the following fields or combinations of fields merely constitutes the intended use of the database. The referenced database is capable of containing medical product information in the fields or combination of fields as disclosed by the claim. Therefore, the following data contained on the database has not been considered because it fails to further limit the system claim, (see MPEP 2106). For examination purposes only, citations have been provided that reference the claimed intended use of the claimed database:

i) product scan codes, (Gombrich, Abstract, col. 2, lines 36-45; col. 9, lines 12-63; col. 14, line 4-col 15, line 47);

ii) product description information including NDC number; wherein said medical product information is specially formatted and designed to support one or more of the items including pharmaceutical calculations, patient care dosing calculations, determination of equivalencies, and proper formatting of text for dosing instructions and directions for use, (Gombrich, Abstract, col. 2, lines 36-45; col. 9, lines 12-63; col. 14, line 4-col 15, line 47);

iii) re-packaging batch identifier codes, (Gombrich, col. 15, lines 15-29, discussing the use of products like unique drugs and custom mixtures that are considered equivalent to re-packaged or admixed products);

iv) re-packaging related product and activity information, (Id.);

v) solution admixture unique container identifier codes, (Id.);

vi) related product and admixture activity information, (Id.);

vii) product recall information, (Mayaud, col. 32, line 22-col. 33, line 34);

viii) company specific data in support of a company's individual product, (Mayaud, Fig. 16; col. 14, lines 32-37; col. 32, line 22-col. 33, line 34; col. 37, lines 17-31; col. 47, lines 47-57; col. 48, lines 9-22)(providing comprehensive scientific, clinical, and commercial drug information from remote source databases);

b) a user access data auditor which provides a user data access audit trail, (Mayaud, col. 47, lines 29-46);

c) a programmed system computer for processing and storing said medical product information, (Mayaud, col. 47, lines 10-20) (prescription information is considered to include medical product information);

d) an input device operatively interconnected to the programmed system computer means, (Mayaud, Fig. 16; col. 45, line 10-col. 46, line 49);

e) an output device operatively interconnected to the programmed system computer means, (Mayaud, Fig. 16; col. 45, line 10-col. 46, line 49);

f) said input and output devices including a plurality of terminals located remotely from the programmed system computer for automatically accessing said database and displaying it to a user, (Mayaud, Fig. 16; col. 45, line 10-col. 46, line 49).

4. As per claim 2, Mayaud discloses a system further comprising an Internet

connection for updating and maintaining medical product information from a remote source database via network data communication, said connection dynamically supplying and automatically updating said product information, (Mayaud, Fig. 16; col. 45, line 10-col. 48, line 8).

5. As per claim 3, Mayaud discloses a system further comprising an Internet connection for updating and maintaining product recall information from a remote source database via network data communication, said connection dynamically supplying and automatically displaying or otherwise using said product recall information to prevent the use of a recalled product, (Mayaud, Fig. 16; col. 32, line 22-col. 33, line 34; col. 45, line 10-col. 48, line 8).

6. As per claim 4, Mayaud discloses a system where said medical product information is concatenated from a plurality of databases selected from the group consisting of a locally-based re-packaging, labeling, and compounding/admixture system, a pharmacy database, and a medication database, (Mayaud, Col. 48, lines 9-col. 49, line 67) (drug information is considered to be product information).

7. As per claim 9, Mayaud discloses a system comprising a source-oriented patient specific data-retrieval subsystem, said data retrieval subsystem being connected to access at least one data-retrieval network to retrieve product description and

identification information and patient-related data to the point of care from at least one remote source database, (Mayaud, col. 5, lines 44-48; col. 45, line 9-col. 47, line 9).

8. As per claim 10, Mayaud discloses a system wherein at least one of said input and output devices is coupled to a voice recognition unit for permitting said user to communicate with said system by means of verbal inputs, (Mayaud, col. 33, lines 1-9).

9. As per claim 11, Mayaud discloses a system wherein said input means further comprises a stylus interface for permitting said user to communicate with said system by writing on said screen with a stylus, (Mayaud, col. 7, lines 46-56; col. 27, lines 4-29).

10. As per claim 12, Mayaud discloses a system wherein information is received in said database input and output devices which utilize one or more of the items taken from the group comprising voice, keyboard, pen and mouse, (Mayaud, col. 33, lines 1-9).

11. As per claim 13, Mayaud discloses a system wherein said medical product information relates to products taken from the group consisting of generic, brand, over-the-counter, biologicals, blood products, medical devices, admixed solutions and total and peripheral parenteral nutrition, (Mayaud, col. 26, lines 6-9) (disclosing medical product information related to generic drugs).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. **Claims 5-9, 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayaud et al., (5,845,255) in view of Gombrich et al., (U.S. 4,835,372).**

13. As per claim 5, Gombrich further discloses a system further comprising a two-way communication means with a locally-based re-packaging, labeling, and compounding/admixture system, (Gombrich, col. 6, lines 40-45; col. 9, lines 12-63; col. 10, lines 16-56; col. 14, line 4-col. 15, line 47; col. 24, lines 9-36).

The statement of obviousness and motivation to combine is as provided in the rejection of claim 6 and incorporated herein by reference.

14. As per claim 6, Gombrich discloses a method for using and creating an institutional level data repository system for medical product information, said method comprising the steps of:

a. calculating and assigning unique batch or container identifier codes to a medical product, (Gombrich, Abstract, col. 2, lines 36-45; col. 9, lines 12-63; col. 14, line 4-col 15, line 47);

b. communicating said codes to a locally-based re-packaging, labeling, and admixture solution system, (Gombrich, col. 6, lines 40-45; col. 9, lines 12-63; col. 10, lines 16-56; col. 14, line 4-col. 15, line 47);

c. receiving, storing and tracking information related to the re-packaging, labeling, and solution admixture activities in support of a bedside scanning medication safety system, (Gombrich, col. 9, line 4-col. 10, line 56;col. 12, line 14-col. 13, line 60).

Gombrich fails to disclose remaining method steps (d) and (e). However, the following steps are well known in the art as evidenced by Mayaud. Mayaud discloses:

d. providing product recall information to prevent administration at the time of use, (Mayaud, col. 32, line 22-col. 33, line 34) (see also Gombrich, col. 15, lines 15-29, discussing the use of products like unique drugs and custom mixtures that are considered equivalent to re-packaged or admixed products); and

e. communicating company specific data in support of the medical product, (Mayaud, Fig. 16; col. 14, lines 32-37; col. 32, line 22-col. 33, line 34; col. 37, lines 17-31; col. 47, lines 47-57; col. 48, lines 9-22)(providing comprehensive scientific, clinical, and commercial drug information from remote source databases).

It would be obvious to one of ordinary skill in the art at the time of the invention to combine Gombrich and Mayaud. The motivation would be to provide relevant drug and

patient information at the time and point of prescription, (Mayaud, col. 1, lines 30-34).

15. As per claim 7, Gombrich further discloses the step of manually entering data using a bar code reader and scanning a bar code on a medication, (Gombrich, col. 15, lines 30-35).

The statement of obviousness and motivation to combine is as provided in the rejection of claim 6 and incorporated herein by reference.

16. As per claim 5, Gombrich further discloses a system wherein at least one of said input and output devices comprises a computer display screen having said medical product information displayed in fields, (Gombrich, Figs. 18, 19; col. 14, line 4-col. 15, line 47).

The statement of obviousness and motivation to combine is as provided in the rejection of claim 6 and incorporated herein by reference.

17. As per claim 14, Mayayd discloses a method further comprising the steps of retrieving medical product information across a network from a remote source database and displaying or allowing access to retrieved product information in real time, (Mayaud, col. 5, lines 44-48; col. 45, line 9-col. 47, line 9).

The statement of obviousness and motivation to combine is as provided in the rejection of claim 6 and incorporated herein by reference.

18. As per claim 15, Mayaud discloses a method wherein said product recall information includes previously known product recall data associated with the product, (Mayaud, col. 32, line 22-col. 33, line 34)(disclosing fully comprehensive and up-to-date databases containing previously known recall information).

The statement of obviousness and motivation to combine is as provided in the rejection of claim 6 and incorporated herein by reference.

19. As per claim 16, Mayaud discloses a method further comprising means for receiving and storing messages relating to product recalls, said messages being automatically displayed to a user at the point of use or upon the identification of said user, (Mayaud, col. 32, line 22-col. 33, line 34)(disclosing a method to lock out the prescribing of recalled drugs).

The statement of obviousness and motivation to combine is as provided in the rejection of claim 6 and incorporated herein by reference.

20. As per claim 17, Mayaud discloses a method further comprising means for receiving and storing messages relating to product recalls, said messages consisting of data comprising at least one of the items selected from the group consisting of: identification of the product, lot number of the product, reason(s) for recall and severity

of recall, (Mayaud, col. 32, line 22-col. 33, line 34) (inherently disclosing a product recall message identifying the recalled product).

The statement of obviousness and motivation to combine is as provided in the rejection of claim 6 and incorporated herein by reference.

21. As per claim 18, Gombrich discloses a method further comprising the steps of reading the identifier code of a dispensed package with a code reader and verifying that the requested package was properly dispensed, (Gombrich, col. 16, line 18-col. 17, line 59).

The statement of obviousness and motivation to combine is as provided in the rejection of claim 6 and incorporated herein by reference.

22. As per claim 19, Gombrich discloses a method wherein the step of verifying the requested package was properly dispensed comprises comparing the code read by the code reader to a reference code, (Gombrich, col. 16, line 18-col. 17, line 59)(scanned drug bar code is matched with patient I.D. bar code and pharmacy-entered drug code prior to administration).

The statement of obviousness and motivation to combine is as provided in the rejection of claim 6 and incorporated herein by reference.

23. As per claim 20, Gombrich further discloses a system further comprising a program operable to use said medical product database and patient specific information to calculate a dosage recommendation, including an amount and a frequency of administration of said medical product, (Gombrich, col. 14, lines 40-64).

The statement of obviousness and motivation to combine is as provided in the rejection of claim 6 and incorporated herein by reference.

24. As per claim 21, Gombrich further discloses a system further comprising communication media for said database containing medical product information to be used with other systems (Gombrich, col. 14, lines 40-64) (disclosing a bar code as a communication medium). Gombrich fails to disclose a system to be used within a local area network. However, such a system is well known in the art as evidenced by Mayaud, (Mayaud, Col. 46, lines 1-22).

The statement of obviousness and motivation to combine is as provided in the rejection of claim 6 and incorporated herein by reference.

25. As per claim 22, Gombrich further discloses a system further comprising communication media for said database containing medical product information to be used with other systems, (Gombrich, col. 14, lines 40-64) (disclosing a bar code as a communication medium). Gombrich fails to disclose a system to be used

in a client server architecture. However, such a system is well known in the art as evidenced by Mayaud, (Mayaud, Col. 46, lines 1-22).

The statement of obviousness and motivation to combine is as provided in the rejection of claim 6 and incorporated herein by reference.

26. As per claim 23, Gombrich further discloses a system further comprising communication media for said medical product information database to support a bedside scanning system for medication safety, (Gombrich, Abstract; col. 2, line1-6, line 54; col. 14, lines 40-64).

The statement of obviousness and motivation to combine is as provided in the rejection of claim 6 and incorporated herein by reference.

Conclusion

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schmitt et al., (U.S. 5,865,745) disclosing a Remote Health Care Information Input Apparatus that has a bar code scanner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell S. Glass whose telephone number is 571-272-3132. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RSG
1/18/06

C. LUKE GILLIGAN
PATENT EXAMINER